Covered stents in aortoiliac occlusive disease

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CHAPTER 3.

Covered stents for aortoiliac reconstruction of chronic occlusive lesions

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ABSTRACT

Aim: Bare metal stents have improved results of endovascular treatment of aortoiliac occlusive disease. Polytetrafluoroethylene covered stents may further improve patency rates by preventing tissue ingrowth, and might reduce complications. This study was conducted to assess possible assets or liabilities of covered stents used for aortoiliac occlusive disease and to conduct a comparison with bare metal stents.

Methods: A review was performed of literature published until March 2012 for infrarenal aortic lesions, iliac lesions and complex aortoiliac lesions. Outcomes were technical success, patency rates, clinical success and complication rates. Results were addressed to the three anatomic regions: the infrarenal aorta, the aortoiliac bifurcation and iliac arteries.

Results: A total of 51 articles were included in the study. Overall technical success varied between 73% and 100%. Randomized data have proven the superiority of covered stents in extensive iliac occlusive lesions. Case series of patients with iliac occlusive disease demonstrated a one-year primary patency of bare metal stents between 76% and 100% with a 5-year primary patency rate of 63%-83%. One-year primary patency of covered stents varied between 70% and 100%, while no long term patency rates with covered stents have been reported so far. Reliable comparisons between groups cannot be made due to variances in patient and lesion characteristics. Covered stents seem to improve results of kissing stents and are related to excellent results in isolated aortic lesions. No difference in complication rate between bare metal and covered stents have been described, to date.

Conclusion: Covered stents improve results of endovascular treatment of extensive iliac occlusive lesions and are related to excellent results in isolated aortic lesions. They may provide a valid alternative for surgery in patients with extensive aortoiliac disease.

INTRODUCTION

Occlusive disease of the abdominal aorta and iliac arteries may cause disabling claudication and critical limb ischemia. In the past decades, treatment modalities have shifted from surgical treatment to endovascular techniques. Guidelines from the Trans Atlantic Inter-Society Consensus II Working Group (TASC-II) recommend endovascular treatment for single or multiple lesions up to 10 cm (TASC A/B lesions), while surgery is advised for bilateral and more extensive lesions (TASC C/D lesions).[1] With the improvement of endovascular techniques and materials, however, endovascular options for aortoiliac occlusive disease are becoming an attractive alternative to surgery even for more complex lesions. Particularly since endovascular techniques might reduce perioperative mortality and morbidity. The 5-year patency rate of surgical reconstruction of aortoiliac occlusion is approximately 91% for patients with claudication and 87% for patients with critical ischemia, respectively. Surgical reconstruction, however, is related to 8.3%-12.2% complication and 3.3-4.4% mortality rates.[2] Moreover, a laparotomy may induce late complications, including incisional hernia and small bowel obstruction, supporting the search for minimal invasive alternatives.

Results of endovascular treatment are affected by a range of factors, including the clinical state of the patient and lesion characteristics. Patency rates are mainly limited by elastic recoil, arterial remodeling and neointimal growth leading to in-stent re-stenosis. Covered stents may shield stents from tissue ingrowth through stent interstices and subsequently reduce re-stenosis caused by intimal hyperplasia.[3-6] In the superficial femoral artery, the use of covered stents has proven to provide equal patency rates as the use of prosthetic bypasses, even at 4-year follow-up.[7]

In this study we have summarized the existing literature on the use of polytetra-fluoroethylene (PTFE) covered stents for the treatment of aortoiliac occlusive disease and made a comparison with the use of bare metal stents for the same purpose.

MATERIAL AND METHODS

A computer assisted search in the medical databases of Medline was conducted. Articles published until March 2012 were included. The search was performed using medical subject headings (MeSH): arterial occlusive disease, iliac artery, aorta, abdominal aorta, occlusion, stenosis, stents, polytetrafluorethylene, polyethylene terephthalate. Free text words were also searched: covered stent, PTFE, Dacron, endovascular, kissing stent,

stent-graft, aortic bifurcation, TASC A/B, TASC C/D. A selection of relevant studies for full text review was made based on title and abstract. Selected articles were hand searched for relevant cross-references.

Articles were included in this review in order of level of evidence, ranked by meta-analyses, randomized controlled trial, large case series and case reports. Exclusion criteria were primary patency less than one year, patency rates not specified for lesion characteristics and/or technique, patency rates based solely on clinical status and/or ankle-brachial index (ABI), other than English language and case reports dealing with less than ten cases, except for those introducing the use of covered stents. Articles of which no full text electronic version was available in two university libraries were excluded.

RESULTS

The infrarenal aorta

Initially, 54 articles were found with the search strategy. Based on abstracts we identified 22 articles that met the inclusion criteria. No full text was available for four articles. Another four articles were excluded since they included extensive disease to iliac arteries. Also, two articles dealing with less than five patients and two articles that did not include patency definitions were excluded. As a consequence, ten articles are included in this review.[8-17] Table 1 presents an overview of these articles.

Focal atherosclerotic occlusive lesions of the infrarenal aorta are a relatively rare manifestation of atherosclerosis and is predominantly seen in relatively young female smokers with elevated lipid profiles. Primary aortic stenting has been related to a one-year primary patency rate of 85% to 100%, as demonstrated in case series.[8-17] Long term follow up has been reported in only three articles, being 60% to 100% after five years.[10,12,14] Literature focusing on eccentric calcified and ulcerative aortic lesions, however, is lacking. Endovascular treatment of focal aortic lesions has been related to a major complication rate up to 16%[15] and may include vessel wall rupture and distal embolization. Vessel wall rupture is more likely to occur with balloon expandable stents as opposed to self expanding stents. The reported complication rates vary between 0% and 28%.[8-17] One death within 30 days of procedure was reported, due to early re-occlusion of the aorta in a patient with a disseminated malignancy.[12]

TABLE 1: Published literature reporting patency rates on focal infrarenal aortic occlusive disease

Study and Year	Type Study	Male/ Female	Mean age (years)	No of lesions	Recurrence stenosis / occlusion	Follow-up (range)	Stent strategy
d'Othee 2002[8]	Cohort	23/12	53 (35-85)	35			Selective
Stoeckelhuber 2003[9]	Cohort	5/4	62	9	0/9	12 (3-20)	Primary
Yilmaz 2004[10]	Cohort	7/6	57	13	0/13	43 (12-96)	Primary
Eftekhar 2004[11]	Cohort	3/4	58	7	0/7	15 (3-42)	Primary
Vallabhaneni 2005[12]	Cohort	5/16	♀ 58 (32-89) ♂ 70 (61-86)	21	1/21		Primary
Poncyljusz 2006[13]	Cohort	7/19	57	26	0/26	18	Primary
Ruppert 2006[14]	Cohort	8/6	62	14	0/14	86 (51-119)	Primary
Moise 2009[15]	Cohort	9/22	63	31		12	Primary
Kim 2011[16]	Cohort	40/9	64 (±11)	49	7/49	42 (0-156)	Primary
Bruijnen 2012[17]	Cohort	3/9	59 (42-78)	12	0/12	8(2-30)	Primary

Study and Year	Type stent (BMS/CS)[c]	SE / BE[d]	Technical success	1 year primary patency	1 year 2ndary patency	4 years primary patency	4 years 2ndary patency	Compli-cations	Distal emboli-zation
d'Othee 2002[8]	Unknown		100%	93%		85% 3y		11.4% (4/35)	0%
Stoeckelhuber 2003[9]	Variety (BMS)	SE/BE	100%	100%				0% (0/9)	0%
Yilmaz 2004[10]	Variety (BMS)	SE	100%	100%		100%		15.3% (2/13)	
Eftekhar 2004[11]	Variety (BMS)	SE	100%	100%				28.5% (2/7)	0%
Vallabhaneni 2005[12]	Variety (BMS/CS)	SE/BE	100%	94%		60%		14.3% (3/21) †1	0%
Poncyljusz 2006[13]	Palmaz (BMS)	BE	100%	100%				7.7% (2/26)	0%
Ruppert 2006[14]	Variety (BMS)	BE/SE	79%	100%		100%		7.1% (1/14)	0%
Moise 2009[15]	Unknown		93%	85%	100%	66% (3y)	90%	16.1% (5/31)	6.3% (2/31)
Kim 2011[16]	Variety (BMS)	BE/SE	82%	70%	96%	64% (3y)	92% (3y)	16.3% (8/49)	10.2% (5/49)
Bruijnen 2012[17]	V12 (CS)	BE	100%	100%				16.7% (2/12)	0%

[a] RCT; randomized controlled trial

[b] HCS; historical cohort study

[c] BMS; bare metal stent, CS; covered stent

[d] SE; self expandable, BE; balloon expandable

To date, only one article has been published on the use of PTFE covered stents for focal infrarenal aortic occlusive disease. In that study, Bruijnen et al. found no re-stenosis, in a group of 12 patients, during a median follow-up of 18 months (range 2-30 months) using the Advanta™ V12 stent (Atrium Medical, Hudson, NH, USA) and no complications were reported.[17] Moreover, no stent fractures were observed at routine follow-up plain abdominal X-ray. Obviously, larger studies and longer follow-up are indicated to assess the role of covered stents in the treatment strategy of these lesions.

The aortic bifurcation

74 articles were identified based on title and after reading of the abstracts 41 articles met the inclusion criteria. Seven articles were not electronically available. 14 articles included cases of occlusive disease restricted to the iliac arteries or abdominal aorta and were therefore excluded. Three reviews (not meta-analysis), one small case series and two articles in which patency rates were not defined were also excluded. In total 14 articles were selected for reviewing. An overview of the results is outlined in Table 2.[8,18-30] A kissing stent technique was used in all but one article and both self expandable and balloon expandable stents were used. In one article the Excluder (W.L. Gore & Associates, Flagstaff, AZ, USA), a PTFE covered endoprosthesis designed for aneurysmal disease, was used. Overall, a technical success was achieved in 73-100% of patients.[8,18-30] Factors that significantly affect patency of stents in a kissing stent configuration are the radial mismatch, defined as the outer stent lumen still being perfused after insertion of kissing stents, and the stent overlap in the distal aorta, thereby creating a flow divider.[21,24,31,32]
A historical cohort study has compared results of PTFE covered stents (Advanta™ V12, Atrium Medical, Hudson, NH, USA) in the kissing stent configuration with the use of bare metal stents.[30] After a median follow-up of 21 months, 22 out of 26 patients (85%) with covered stents had sustained improvement in clinical symptoms compared with 15 of 28 patients (54%) treated with bare metal stents (P=.02). Primary patency rates at 1 and 2 years were 92% and 92%, respectively, for covered stents and 78% and 62% for bare metal stents (P=.02). The complication rate was not significantly different between groups.
The reported primary patency rates, in mainly cohort studies, of bare metal stents were 76-100% at one year[8,18-20,22,25,27,30], 58-94% at two years[8,19,20,22,24,30] and 63% at five years.[25] Reported primary patency rates of covered stents were 70-92% at one year[28,30] and 92% at two years.[30] Secondary patency rates of bare metal stents are 84-100% at one year[18,20,22,23,25,27], 65-98% at two years[20,22-24] and 81% at five years.[25] One study

reported a one year secondary patency rate of covered stents of 88%.[28] Reported complication rates of bare metal kissing stents vary between 6.2 and 23.5%.[8,18-22,24-27] Distal embolization was reported up to 8.3%.[21] Two out of 651 patients died within 30 days post procedural, one due to myocardial infarction, the other due to complications of metastatic lung cancer.[18,28]

In another article the Excluder endoprosthesis (W.L. Gore & Associates, Flagstaff, AZ, USA) was used for occlusive disease in five patients. It was related to 100% technical success and hemodynamic success in all patients. All aortoiliac reconstructions remained patent during a mean follow-up of 17 months.[29]

The iliac arteries

One-hundred-twenty-six articles were identified based on title. After reading of abstracts, 76 articles were selected for full text reading. Full text versions were not available for 20 articles. 18 articles were excluded because patency rates were not stated, or not clearly defined. Furthermore, six articles dealing with complex aortoiliac disease, two articles focusing on another subject, two reviews and one case series with less than ten patients were excluded. In total 27 articles were selected for further assessment.[33-59] Most articles focused on the use of bare metal stents in either a selective or a primary stent strategy, three articles described results of PTFE covered stents. A summary of results is shown in Table 3.

The outcome of iliac stenting may depend on various factors including anatomical aspects, the clinical state of the patient and the choice of stent strategy. A recent meta-analysis showed that a primary stent strategy is related to a higher patency rate within the first three years when compared to a selective stenting strategy for TASC C and D lesions.[59] After five years, however, there was no difference between both strategies.[59] The Dutch Iliac Stent Trial (DIST), however, provided evidence supporting a selective stenting strategy for patients treated for intermittent claudication.[39] A historic cohort study showed that with the use of bare metal stents in a primary stent placement strategy there was no significant difference in technical success or patency rates up to ten years between TASC A/B and TASC C/D lesions (71% vs. 83%, respectively).[53]

TABLE 2: Published literature reporting patency rates on aortoiliac complex occlusive disease

Study and Year	Type Study	Male/ Female	Mean age (years)	No of lesions	Recurrence stenosis / occlusion	Follow-up (range)	Stent strategy
Houston 1999[18]	Cohort	13/20	64	33	3/33	16 (12-26)	Selective/ primary
Scheinert 1999[19]	Cohort	29/19	59 (38-78)	48	3/48	24 (6-56)	Primary
d'Othée 200[28]	Cohort	15/2	51 (25-66)	17			Selective
Mohammed 2002[20]	Cohort	12/12	66 (48-87)	24	7/21	23 (3-36)	Primary
Brittenden 2002[21]	Cohort	5/7	62 (43-73)	12	9/12	27 (2-70)	Primary
Haulon 2002[22]	Cohort	97/9	52 (33-78)	106	15/106	30 (12-137)	Primary
Greiner 2003[23]	Cohort	15/10	61 (44-86)		4/21	16 (9)	Primary
Greiner 2005[24]	Cohort	22/19	55 (32-77)	70		35 (3-132)	Primary
Yilmaz 2006[25]	Cohort	64/4	64	68	16/68	36 (1-144)	Primary
Bjorses 2008[26]	Cohort	80/93	64 (±12)			14 (2-26)	Primary
Krankenberg 2009[27]	Cohort	8/3	63 (40-101)		2/11	21	Primary
Rzucidlo 2003[28]	HCS[b]	34	58	59		17 (3-36)	Primary
Maynar 2005[29]	Cohort	3/2	61 (39-79)	5	0/5	20 (1-62)	Primary
Sabri 2010[30]	HCS[b]	PTFE 17/9 BMS 15/13	61 (38-82)			21 (1-62)	Primary Primary

TABLE 2: Published literature reporting patency rates on aortoiliac complex occlusive disease

Study and Year	Type stent (BMS/CS)[c]	SE / BE[d]	Technical success	1 year primary patency	1 year 2ndary patency	4 years primary patency	4 years 2ndary patency	Compli-cations	Distal emboli-zation
Houston 1999[18]	Memo-therm (BMS)	SE	100%	89%	93%			15.1% (5/33) 1†	0%
Scheinert 1999[19]	Palmaz (BMS)	BE	100%	97%				6.2% (3/48)	0%
d'Othée 200[28]	Variety (BMS)		100%	94%		86% 3y		23.5% (4/17)	
Mohammed 2002[20]	Variety (BMS)	SE/BE	100%	82%	84%	58% 3y	84% 3y	20.8% (5/24)	
Brittenden 2002[21]	Variety (BMS)	SE/BE	100%					16.7% (2/12)	8.3% (1/12)
Haulon 2002[22]	Variety (BMS)	SE/BE	100%	90%	100%	79% 3y	98% 3y	7.1% (15/106)	0%
Greiner 2003[23]	Variety (BMS)	SE/BE	86%		91%				
Greiner 2005[24]	Variety (BMS)	SE/BE	92%					12% (9/76)	
Yilmaz 2006[25]	Variety (BMS)	SE/BE	100%	76%	94%	63% 5y	81% 5y	12% (8/68)	2.9% (2/68)
Bjorses 2008[26]	Variety (BMS/CS)	SE/BE	99%	97%	100%	65% 5y	83% 5y	8.6% (15/173)	1.7% (3/173)
Krankenberg 2009[27]	Variety (BMS)	SE/BE	73%	100%	100%			9.1% (1/11)	
Rzucidlo 2003[28]	Wallgraft/ Viabahn (CS)	SE	100%	70%	88%			5.9% (2/37) †1	
Maynar 2005[29]	Excluder (CS)	SE	100%	100%				0%	
Sabri 2010[30]	iCAST (CS) Variety (BMS)	BE BE	100% 100%	92% 78%				11% (3/26) 7% (2/28)	

[a] RCT; randomized controlled trial

[b] HCS; historical cohort study

[c] BMS; bare metal stent, CS; covered stent

[d] SE; self expandable, BE; balloon expandable

The overall technical success rate of bare metal stent placement was 83-100%[33-37,41-43,45-53], which was related to clinical benefit in 76-91% of the treated patients.[33,35,38,41,43,45,50] For the use of covered stents, technical success rate of 97-100%[54-57] was reported. In one article clinical benefit in all patients was described.[55] The reported one-year primary patency rate of bare metal stents varied between 78-97%[33,35-48,50-53] with a secondary patency of 86-99%.[34,36,37,42-44,46,48,51,53] Five-year primary and secondary patency rates of bare metal stents were 69-83%[47,50,51,60] and 86%[51], respectively. Three reports mentioned ten-year primary patency and secondary patency rates of 46-83%[44,53,60] and 55-98%[44,53], respectively. Various case series have been published on the use of covered stents for occlusive iliac artery disease.[54-57] These studies have shown a one-year primary patency rate between 84% and 100%, with a secondary patency of 100%. In a prospective non-randomized trial, Bosiers et al. have demonstrated a 91% primary patency rate at one year in a series of 91 limbs in 65 patients.[55] In a retrospective analysis, we have recently described a primary patency of 89% at one year, 86% at two years and 72% at four years, respectively, in a group of 69 primary endograft placements using a primary stenting strategy.[61] Patients that were treated after previous bare metal stent placement had significantly lower primary patency rates, with 78% at one year, 72% at two years and 53% at four years, respectively. This emphasizes the importance of choosing the right treatment strategy for each patient and urges the need to identify those patients that might benefit from covered stents. Drawback of this study was that the majority of patients were treated for TASC A and B lesions.

The Covered Versus Balloon Expandable Stent Trial (COBEST) was the first randomized controlled trial to compare covered stents with bare metal stents in the management of aortoiliac occlusive disease.[58] One-hundred-sixty-eight iliac arteries in 125 patients were randomly assigned to be treated with a covered stent (Advanta™ V12, Atrium Medical, Hudson, NH, USA) or a bare metal stent. Lesions treated with a covered stent were significantly more likely to remain free from re-stenosis at 18 months than those treated with a bare metal stent. Freedom from occlusion was higher in lesions treated with covered stents compared to those treated with a bare-metal stent, but not reaching statistical significance. Subgroup analyses demonstrated a significant difference in freedom from re-stenosis for covered stents in TASC C and D lesions compared with bare metal stents. This difference was not demonstrated for TASC B lesions. The authors concluded that covered stents perform better for TASC C and D lesions than bare metal stents with regard to patency and clinical outcome. A bias of this study may have been

that the control arm existed of a variety of bare metal stents. Additional comparative studies should confirm these observations indicating the superiority of covered stents in extensive lesions, as seems to be true for other arterial segments.

The overall complication rate of bare metal stenting was between 2.7 and 24%[33-39,41-47,49-53] and distal embolization was present in 0-9% of cases.[34-38,41-43,45-47,49,51-53] Only two patients (of 3343) deceased within 30 days after the procedure, and both were not procedure related.[36,41] A historic cohort study compared results of a selective stent strategy, using bare metal stents, to surgical reconstruction with bypass for TASC B and C lesions.[47] Initial primary patency at one year did not significantly differ between groups (85% for selective stenting versus 89% for surgical bypass), but primary patency at five years was 69% for selective stenting and 86% for surgical bypass. Complication rates in these groups were 14.6% in endovascular treatment versus 13.3% for surgical bypassing.

DISCUSSION

In this review we provided an overview of current literature on the efficacy of the use of bare metal and covered stents for aortoiliac occlusive disease. Randomized data have proven the superiority of covered stents in extensive iliac lesions, in which surgery should be considered, hereby providing a treatment modality associated with less morbidity and mortality. Moreover, covered stents are related to an improved outcome in a kissing stent configuration and related to excellent results in isolated aortic lesions. The review of literature showed that little uniformity in various series exists. Different anatomic lesions, strategies, clinical states and materials were reported together in single cohort studies. Therefore, any comparison between case series of bare metal stents and covered stents may not be reliable.

Endovascular techniques have been advised for short, focal aortoiliac lesions by the TASC working group, while for more complex and diffuse lesions surgical intervention is advised.[1] Indeed, the five-year estimated limb based patency in surgical bypass is 91.0% (range 64.3%-95.4%),[2] compared to a five year secondary patency of 83.0% (range 73.0%-89.8%) after endovascular treatment with bare metal stents for TASC C/D lesions.[59] The higher patency rate of open repair is however accompanied by a mortality rate of 3.3-4.4% and complication rate of 8.3%-12.2%.[2] The observed complication rates with bare metal stents in this study varied from 0% to 28% and of covered stents from 0% to 13%.

Table 3: Published literature reporting patency rates on iliac artery occlusive disease

Study and Year	Type study	Male/ Female	Mean age (years)	No of lesions	Recurrence stenosis / occlusion	Follow-up (range)	Stent strategy
Raillat 1990[33]	Cohort	16/0	50 (38-65)	23	5/16	(6-24)	Selective
Vorwerk 1992[34]	Cohort	125	57 (40-73)	125	12/123		Selective
Palmaz 1992[35]	Cohort	486	63 (±10)	587	16/201	9 (1-35)	Primary
Murpy 1996[36]	Cohort	47/19	63±11	94		14 (±8)	Selective
Sapoval 1996[37]	Cohort	84/11	52(35-82)	101	29	29(2-44)	Primary
Sullivan 1997[38]	Cohort	178/110	63	424		11 (0-40)	Primary
Tetteroo 1998[39]	RCT[a]	102/41 99/37	59 (±11) 60 (±11)	187 65			Primary/ Selective
Lee 2000[40]	HCS[b]	69 male	CIA 66 (±1) EIA 69(±1)	37 61		21 (2)	Primary
Yoon 2001[41]	Cohort	24/1	66 (54-83)	30	7/30	20 (8)	Primary/Selective
Uher 2002[42]	Cohort	40/33	64 (42-89)	76	16/76	27 (1-75)	Primary
Siskin 2002[43]	Cohort	29/13	46 (33-50)	59	7/59	19 (1-67)	Primary/Selective
Schurmann 2002[44]	Cohort	88/22	57 (40-73)	126		68 (0-144)	Selective
Reekers 2002[45]	Cohort	126		153		>12	Selective
Funovics 2002[46]	Cohort	78	61 (36-88)	80		24 (18)	Primary
Timaran 2003[47]	HCS[b]	PTA 136 (78/43) Bypasss 52 (27/25)	59 (36-88)	PTA 178 Bypasss 60			Selective/ Surgical Bypass
Ponec 2004[48]	RCT[a]	Smart 64/38 Wall 62/39	66(±11) 67 (±10)	103 102		12	Selective Selective
Park 2005[49]	Cohort	197/203		249	26/203	31 (1-120)	Primary
AbuRahma 2007[50]	HCS[b]	Sel 19/22 Prim 57/53		41 149		34 (1-66) 24 (1-81)	Selective Primary

TABLE 3: Published literature reporting patency rates on iliac artery occlusive disease

Study and Year	Type stent (BMS/CS)[c]	SE/ BE[d]	Technical success	1 year primary patency	1 year 2ndary patency	4 years primary patency	4 years 2ndary patency	Compli-cations	Distal emboli-zation
Raillat 1990[33]	Wallstent (BMS)	SE	100%	84%				18.8% (3/16)	
Vorwerk 1992[34]	Wallstent (BMS)	SE	100%		98%			4% (5/125)	2.4% (3/125)
Palmaz 1992[35]	Palmaz (BMS)	BE	100%	92%				9.9% (58/587)	1.0% (6/587)
Murpy 1996[36]	Wallstent (BMS)	SE	91%	78%	86%			9% †1 (8/94)	2.1% (2/94)
Sapoval 1996[37]	Wallstent (BMS)	SE	99%	80%	90%	61%	86%	11.9% (12/101)	8.9% (9/101)
Sullivan 1997[38]	Wallstent/ Palmaz (BMS)	SE/BE		81%				14.1% (44/312)	0.3% (1/312)
Tetteroo 1998[39]	Palmaz (BMS)	BE		80% 81%				4% (7/187) 7% (5/65)	
Lee 2000[40]	Wallstent/ Palmaz (BMS)	SE/BE		88% 93%		78% 3y 90% 3y			
Yoon 2001[41]	Niti-S (BMS)	SE	100%	96%		86% 3y		8.3% (2/24) 1†	0%
Uher 2002[42]	Variety (BMS)	SE/BE	97%	79%	87%	69%	81%	10% (7/73)	2.7% (2/73)
Siskin 2002[43]	Variety (BMS)	SE/BE	95%	86%	90%	65% 3y	88% 3y	16.7% (7/42)	0%
Schurmann 2002[44]	Wallstent (BMS)	SE		92%	96%	71% 46% 10y	83% 55% 10y	8.2% (9/105)	
Reekers 2002[45]	Cordis Perflex (BMS)	BE	100%	89%				8% (10/126)	1.5% (2/126)
Funovics 2002[46]	Variety (BMS)	SE/BE	95%	78%	89%	64%	78%	16.6% (13/78)	9.0% (7/78)
Timaran 2003[47]	Variety (BMS)	SE/BE	96%	85% 89%		69% 5y 86%		14.6% (26/178) 13.3% (8/60)	0.1% (1/178)
Ponec 2004[48]	Smart (BMS) Wallstent (BMS)	SE SE	98% 88%	95% 91%	98% 98%				
Park 2005[49]	Variety (BMS)	SE/BE	98%			83% 5y 49% 10y		6% (12/203)	0.2% (5/203)
AbuRahma 2007[50]	Variety (BMS) Variety (BMS)	SE/BE	83% 97%	83% 98%		69% 5y 77% 5y		24% (10/41) 2.7% (3/110)	

Study and Year	Type study	Male/ Female	Mean age (years)	No of lesions	Recurrence stenosis / occlusion	Follow-up (range)	Stent strategy
Carreira 2008[51]	Cohort	25/1		31			Selective
Stockx 2010[52]	Cohort	113/38	60 (±8)	163			Primary
Ichihashi 2011[53]	HCS[b]	367/46	71(±8)	533		72 (1-144)	Primary
Wiesinger 2005[54]	Cohort	51		60	4/60	12	Primary
Bosiers 2007[55]	Cohort	51/40	65	91	6/91	8 (0-21)	Primary
Cerezo 2008[56]	Cohort	14/1	67 (±7)	15			Primary
Giles 2008[57]	Cohort			40			Primary

Study and Year	Type stent (BMS/CS)[c]	SE/ BE[d]	Technical success	1 year primary patency	1 year 2ndary patency	4 years primary patency	4 years 2ndary patency	Compli-cations	Distal emboli-zation
Carreira 2008[51]	Symphony (BMS)	SE	100%	97%	97%	79% 76% 5y	90% 86% 5y	9.6% (3/31)	0%
Stockx 2010[52]	Express LD (BMS)	BE	98%	89%				0.7% (1/151) MAEe	0%
Ichihashi 2011[53]	Variety (BMS)		TASC A/B 99% TASC C/D 99%	90% 95%	99% 99%	71% 10y 83% 10y	98% 10y 97% 10y	3.1% (9/290) 8.8% (11/125)	1.4% (4/290) 2.4% (3/125)
Wiesinger 2005[54]	Cordis nitinol (CS)	SE	99%		90.7%			1.7% (1/60)	0%
Bosiers 2007[55]	V12 (CS)	BE	100%	91%				0%	0%
Cerezo 2008[56]	V12 (CS)	BE	100%	100%	100%			13.3% (2/15)	0%
Giles 2008[57]	iCast (CS)	BE	97%	84%	100%				

[a] RCT; randomized controlled trial

[b] HCS; historical cohort study

[c] BMS; bare metal stent, CS; covered stent

[d] SE; self expandable, BE; balloon expandable

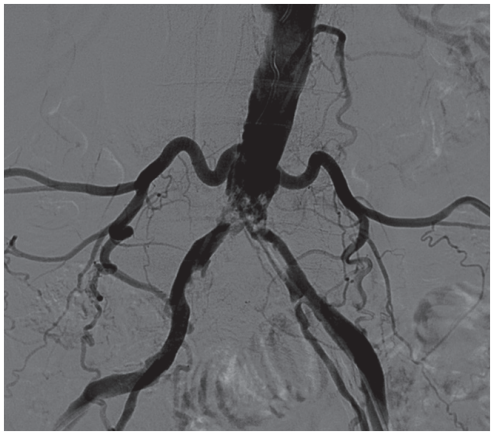
The COBEST trial has shown a superiority of covered stents in these TASC C/D lesions.[58] Therefore, endografts might provide an extra endovascular treatment option for these, often frail, patients, although comparative studies with surgery have not been conducted. This study has also supported the hypothesis that covered stents should be reserved for more extensive lesions. A recent study of our group emphasized the need for proper patient selection as secondary procedures perform worse compared to primary procedures.[61]

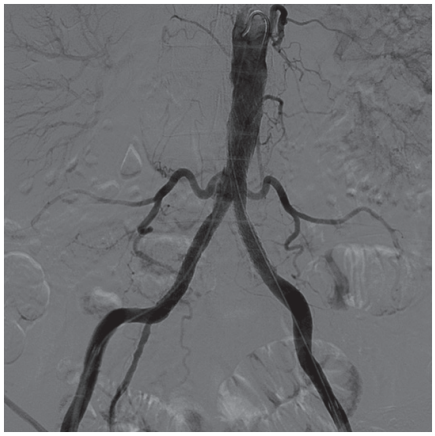
One of the theoretical advantages of covered stents is that they might reduce complications, including embolization and rupture. The reported incidences of these complications did not seem to differ between the cohorts treated with bare metal and covered stents. The heterogeneity of these case studies, however, renders this comparison unreliable. The only randomized study neither showed any difference in complication rates between covered and bare metal stents.[58] This study, however, may well have been underpowered to show such a difference.

Disadvantages of covered stents include the possible covering of collaterals and increased costs. In the present study we could not find an increased amputation rate in case of failure of a covered stent compared to bare metal stenting. In both groups the incidence

was very low. Moreover, the most important collateral in the iliac artery, the hypogastric artery, is often spared. Whether the use of covered stents for chronic occlusive aortoiliac lesions is cost-effective may not be concluded from the present data. The use of covered stents is likely to increase procedural costs. Additionally, endovascular techniques are often related to a higher incidence of re-interventions in order to maintain patency, when compared to surgery. On the other hand, the mean hospital stay and complication rate is usually lower, due to its minimal invasive character. Further studies, focusing on cost-effectiveness are indicated.

For extensive aortoiliac disease involving the bifurcation a kissing stent configuration is frequently used.[62] Patency rates are affected by radial mismatch and stent overlap in the distal aorta.[24,63] The use of PTFE covered stents seem to be related with a better outcome, both clinically and hemodynamically. In a case control study, the use of PTFE covered stents led to a two year primary patency rate of 92% versus 62% for bare metal stents, while the complication rate was not significantly different.[30] The use of the Excluder endograft was also related to a favorable outcome in a small series of patients.[29] The use of devices, developed for aneurysm disease, however, does not seem to be a legitimate strategy. Radial strength is usually too low to overcome a heavily calcified lesion and moreover the design of the endograft could complicate the procedure. As both the ipsi- and contralateral limb deploy at the same time, cannulation of the contralateral limb in an occluded aorta may not be feasible. Therefore, the Endovascular Reconstruction of the Aortic Bifurcation (CERAB) technique was developed. Using this technique, the bifurcation is reconstructed using three balloon expandable PTFE covered stents. First, a balloon expandable PTFE covered stent is placed in the aorta. Proximally, the stent is flaired, thereby creating a cone shape. In the 12 mm distal portion of the aortic stent two PTFE covered kissing stents are deployed, moulding the aorta stent around the latter two (fig. 1A and 1B). In this way the radial mismatch is minimized, possibly improving patency rates. Initial results of this technique have however not been published to date and must be awaited.





1A 1B

Figure 1A Pre-procedural angiography of a 56-year old patient, with a history of hypertension and nicotine abuse presenting with Rutherford 3, not responding to walking exercise training.

A heavily calcified lesion in the distal aorta was found extending into both common iliac arteries

Figure 1B Post-procedural angiography after covered endovascular reconstruction of the aortic bifurcation (CERAB). First a 12 mm covered stent (Advanta™ V12, Atrium Medical, Hudson, NH, USA) was inserted in the distal aorta. Subsequently the proximal 2/3 was post-dilated to 16mm, thereby creating a tapered endograft. Afterwards, two 8mm stentgrafts were placed in the first stentgraft and were simultaneously inflated thereby folding 12mm part of the first stent around the latter two.

In conclusion, covered stents improve results of endovascular treatment of extensive iliac occlusive lesions and are related to excellent results in isolated aortic lesions. They may provide a valid alternative for surgery in patients with extensive aortoiliac disease. Results of new techniques, including the CERAB reconstruction should be awaited.

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